

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth M. Adams et al.	Examiner:	Mary C. Hoffman
Serial No.:	10/657,915	Group Art Unit:	3733
Filed:	September 9, 2003	Docket No.:	M190.145.101
Due Date:	February 5, 2010 (w/one mo. extension)		
Title:	SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please consider the following remarks during the Pre-Appeal Brief Conference. As these remarks outline a clear legal or factual deficiency in the rejections, Applicant submits that the Pre-Appeal Brief Request for Review is appropriate.

The Claimed Invention

The present application is directed to a surgical cutting instrument and, in particular, a distal section configuration of the instrument that utilizes a bur in combination with an opening and elevator tip. Claim 1 clearly recites a distal section that includes a proximal zone, an intermediate zone and "a distal zone extending from the intermediate zone to a distal-most end of the pocket at which the central lumen terminates". Moreover, claim 1 clearly recites an elevator tip extending distal the pocket. One embodiment of the claimed invention is shown below, clearly pointing out an example of the claimed features of the distal section.

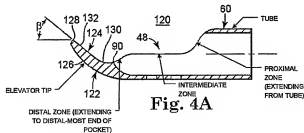


Fig. 4A

Claim Rejections under 35 U.S.C. § 102

In the Final Office Action, claims 1, 10, 13, 15-20, 22-23, 31-32 and 34-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ancil et al. (U.S. Patent No. 5,922,003) ("Ancil"). For reasons provided below, the claimed features shown above are clearly

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Docket No.: M190.145.101

Title: SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY

distinguished from Ancil. The disclosure of Ancil is primarily directed to an angled rotary tissue cutting instrument and is concerned with various embodiments that are directed to locations of bends along the cutting instrument and configuring outer and inner tubular members to conform to a desired bend. Of the different embodiments, Ancil illustrates three different distal end configurations.

With specific regard to the distal end configurations that are disclosed, Ancil notes that the distal end of an outer tubular member is suitably configured to cooperate with a particular configuration of a distal end of the inner tubular member. *See Ancil*, col. 9, l. 66 to col. 10, l. 4. That is, depending on a particular cutting element, a particular window configuration is chosen. In FIG. 1 (reproduced below), a serrated window 30 is used with a serrated cutting tip 38. Alternatively, in the embodiment shown in FIG. 20 (reproduced below), wherein a bur 788 is utilized, cutting window 730 is suitably configured in a large, open configuration open at its distal end so as to accommodate bur 788. The embodiment in FIG. 26 (reproduced below) illustrates yet another alternative embodiment, wherein a small hemispherically shaped opening 830 is positioned at a distal end in order to accommodate cutting tip 838.

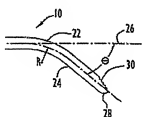


FIG. 1

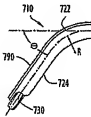


FIG. 20

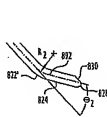


FIG. 26

In the Office Action, the Examiner has arbitrarily chosen features from these separate and distinct embodiments in order to create different window configurations that are not particularly disclosed. Moreover, it appears that the Examiner has used impermissible hindsight in an attempt to reject the features of claim 1. For example, the embodiment of FIG. 1 does not include a bur or exposing a bur relative to an outer tubular member. Furthermore, it does not appear that the embodiment of FIG. 1 would accommodate a bur. The embodiment of FIG. 20, which does illustrate a bur, does not disclose three separate zones or a pocket with an elevator tip distal the pocket. Even if one were to put serrations on window 730 in the embodiment of

Pre-Appeal Brief Request for Review

Applicant: Kenneth M. Adams et al.

Serial No.: 10/657,915

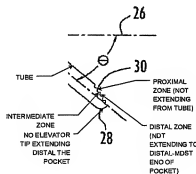
Filed: September 9, 2003

Docket No.: M190.145.101

Title: SURGICAL MICRO-BURRING INSTRUMENT AND METHOD OF PERFORMING SINUS SURGERY

FIG. 20, window 730 would still not include an elevator tip that extends distal a pocket. The embodiment of FIG. 26 does not disclose three separate zones, an elevator tip or a bur.

In any event, the Examiner continues to maintain that the serrations of FIG. 1 of Ancil and bur of FIG. 20 of Ancil teach the features of claim 1. Applicants disagree and submit that the serrations of Ancil simply fail to teach or reasonably make obvious the proximal, intermediate and distal zones or the elevator tip as claimed. First, the alleged proximal zone of Ancil pointed to in the Office Action does not extend from the proximal portion as defined in claim 1. Instead, the alleged proximal zone is arbitrarily chosen as positioned somewhere between an intermediate section of an outer tubular member and the alleged intermediate zone of the distal section. Thus, the alleged proximal zone of Ancil does not extend “downwardly from the proximal portion” as recited in claim 1. In addition, Ancil clearly does not teach or reasonably make obvious an elevator tip as disclosed and claimed. The Official Action merely alleges that the “distal-end of device” describes an elevator tip. Applicant respectfully disagrees and notes the distal-end of the Ancil device merely forms an end of the pocket and does not extend in an elevated fashion distally from the pocket. As is best understood from the drawing provided in the Office Action, below is a reproduction of the alleged teachings of Ancil.



Based on the above drawing, the serrations of Ancil simply fail to teach or reasonably make obvious the distal section recited in claim 1. Simply, there is no objective evidence in Ancil of proximal zone extending from a tube, a distal zone extending to a distal-most end of a pocket or an elevator tip extending distal the pocket.

In the Advisory Action dated December 30, 2009, the Examiner points to column 13, lines 33-39 of Ancil as noting that features of various embodiments can be combined. However, the combinations are clearly limited “dependent upon the operational requirements for

Pre-Appeal Brief Request for Review

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Docket No.: M190.145.101

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the procedure to be performed" and not in any arbitrary manner as the Office Action suggests. In fact, Ancitil notes that an opening in the outer tubular member is suitably configured to cooperate with the particular configuration of the inner tubular member. To this end, Ancitil fails to teach any configuration that utilizes a bur and a pocket/distal elevator tip as recited in claim 1 and does not explicitly disclose that a bur can be utilized in the FIG. 1 distal configuration. As a result, the rejection to claim 1 appears to be strictly based on hindsight and not on explicit disclosure in Ancitil. Thus, withdrawal of the rejection to claim 1 is requested.

Moreover, several of the dependent claims are neither taught nor suggested by the distinct distal configurations provided in Ancitil. For example, claim 13 recites that the intermediate zone is parallel with the central axis of the proximal portion. However, in the serrated illustration provided by the Examiner, the intermediate zone is not parallel with a central axis of the proximal portion. Thus, this feature is separately patentable over Ancitil.

With regard to claim 19, the aspiration passage of Ancitil is simply not formed at a distal end of the bur as illustrated in FIG. 23. Instead, a hole 750 is formed proximal to the distal end of the bur. As a result, the disclosure of Ancitil does not support a rejection of claim 19 and thus is separately patentable.

With regard to claim 23, the Examiner has not provided any objective evidence that discloses where the elevator tip is selectively axially moveable to the bur. Instead, it appears that the alleged elevator tip, which is simply the end of the outer tube, is fixed relative to the bur. Thus, claim 23 is separately patentable.

With regard to claim 31 and 32, the angled serrated opening as illustrated in FIG. 1 of Ancitil does not include a bur. Thus, these features are patentable over Ancitil.

For at least the reasons provided above, claims 1, 10, 13, 15-20, 22-23, 31-32 and 34-36 are allowable over Ancitil. Withdrawal of the rejections to these claims is requested.

35 U.S.C. §103 Rejections

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ancitil. Furthermore, claims 2-9, 11-12 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ancitil in view of Adams, U.S. Patent No. 6,503,263. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ancitil in view of West, Jr., U.S. Patent No. 5,364,395. These claims are patentable at least based on their relation to claim 1.

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Furthermore, with regard to claim 33, the only embodiment in Anctil or Adams that illustrates a distal end opening such that the distal most end is below a central axis of the lumen is FIG. 20. However, FIG. 20 does not suggest an elevator tip extending distal a pocket or the separate zones as recited. Instead, bur 788 is open on all sides at a distal end so as to cooperate with the opening 730. No suggestion for utilizing a pocket configuration as recited in claim 33 is provided. For at least these reasons, claim 33 is separately patentable.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-13, 15-24 and 31-36 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-13, 15-24 and 31-36 are respectfully requested.

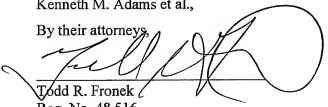
Applicants hereby authorize the Commissioner for Patents to charge Deposit Account No. 50-0471 in the amount of \$130.00 to cover the fees as set forth under 37 C.F.R. 1.16(h)(i).

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Todd R. Fronek at Telephone No. (612) 767-2522, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,
Kenneth M. Adams et al.,
By their attorneys,


Todd R. Fronek
Reg. No. 48,516

Date: 9/5/10
TRF:skh